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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,193	07/18/2003	Brad S. Culbert	TRIAGE.021A	2665

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EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,193

Applicant(s)

CULBERT ET AL.

Examiner

Anu Ramana

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
4a) Of the above claim(s) 1-17, 24, 25, 29 and 30 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 18-20, 23 and 26 is/are rejected.
7) ☒ Claim(s) 21, 22 and 28 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 7/18/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/18/06; 5/18/04; 5/10/04; 11/20/03
4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the invention of Group II (claims 18-28) in the reply filed on March 3, 2006 is acknowledged. Accordingly, claims 1-17 and 29-30 are withdrawn from further consideration as being drawn to a nonelected invention.

Applicants' elected species 4 (Figs. 6E-6F) during a phone conversation on June 6, 2006 (see attached Interview Summary Form). Accordingly, claims 24, 25 and 27 are withdrawn from consideration since they are directed to nonelected species. Claims 18-23, 26 and 28 have been examined on the merits in this office action.

Claim Objections

Claim 28 is objected to because of the following informalities. In line 11, insert - - portion of the - - after "first" and before "fixation" and in line 14, insert - - portion of the - - after "second" and before "fixation" to be consistent with the earlier recitation of the first and second portions of the fixation structure. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18, 23 and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 11/056,991 ('991 herein) in view of Cachia (US 5,893,850).

Claim 3 of '991 discloses all elements of the claimed invention except for a bone anchor at the distal end of the stabilization or "fixation" device.

Cachia discloses a fixation device having a distal and a proximal anchor wherein the distal anchor is used to resist proximal withdrawal of the fixation device from the through hole in which it is placed (see discussion of Cachia on pages 4 and 5 of this office action).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a distal anchor, as taught by Cachia, on the stabilization device of claim 3 of '991, to resist proximal withdrawal of the stabilization device.

The method steps of claims 18, 23 and 26 are rendered obvious by the above discussion.

This is a provisional obviousness-type double patenting rejection.

Claims 19 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 11/056,991 ('991 herein) and Cachia (US 5,893,850), as applied to claim 18, further in view of Ray (US 5,527,312).

The combination of claim 3 and Cachia discloses all elements of the claimed invention except for insertion of the fixation device through a facet of a first vertebra and a pedicle of a second vertebra.

Ray teaches a method of spinal fixation wherein a fixation device is placed through a facet of a first vertebra and a pedicle of a second vertebra for fixing a first vertebra with respect to a second vertebra for holding the same to facilitate fusion.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the method of the combination of claim 3 of '991 and Cachia to place a fixation device through a facet of a first vertebra and a pedicle of a second vertebra, as taught by Ray, to fix a first vertebra with respect to a second vertebra to facilitate fusion.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-20, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ray (US 5,527,312) in view of Cachia (US 5,893,850).

Ray discloses a method of spinal fixation wherein an anchor portion of a fixation device is advanced through a facet of a first vertebra and the pedicle of a second vertebra (Fig. 1, col. 2, lines 26-67 and col. 3, lines 43-50).

Ray discloses all elements of the claimed invention except for the steps of: (1) advancing a proximal anchor distally along a fixation device; and (2) retracting the body of the fixation device with respect to the proximal anchor.

Cachia teaches a pin or "fixation device" 24 having a distal anchor 34 that is placed through a predrilled bore wherein a proximal anchor 36 may be placed after placement of the fixation device and proximal traction is applied to the fixation device to seat the distal anchor 34 of the fixation device (col. 4, lines 13-22 and col. 7, lines 13-40).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted an anchor as, for example, taught by the Cachia reference for the anchor of the Ray device wherein so doing would amount to mere substitution of one functionally equivalent fixation device for another within the same art and the selection of any of these fixation structures would work equally well in the Ray device.

The method steps of claim 18-20, 23 and 26 are rendered obvious by the above discussion.

Allowable Subject Matter

Claims 21 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 28 would be allowed if the objection made in this office action were addressed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR

Anuradha Ramana

June 10, 2006